

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

# otosil IS-2

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Relevant identified uses:** Manufacture.  
**Uses advised against:** Private households (= general public).

### 1.3. Details of the supplier of the safety data sheet

#### Manufacturer

pro3dure medical GmbH

Am Burgberg 13  
D 58642 Iserlohn

**Telephone** +49 (0)2374 920050-10

**Telefax:** +49 (0)2374 920050-50

#### Supplier

pro3dure medical GmbH

Am Burgberg 13  
D 58642 Iserlohn

**Telephone** +49 (0)2374 920050-10

**Telefax:** +49 (0)2374 920050-50

#### Information contact

pro3dure medical GmbH

**Information telephone** +49 (0)2374 920050-10

**Information telefax** +49 (0)2374 920050-50

**E-mail (competent person)** info@pro3dure.com

**Website** www.pro3dure.com

### 1.4. Emergency telephone number

pro3dure medical GmbH  
This number is serviced during office hours.

**Telephone** +49 (0)2374 920050-10

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008:  
Identification is not obligatory. Please observe the information on the safety data sheet at all times.

### 2.2. Label elements

Classification according to Regulation (EC) No 1272/2008 [CLP]

Hazard pictograms

Signal word:

Hazard statements:

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Precautionary statements:

-

**Special labelling of particular preparations:**  
none

## 2.3. Other hazards

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## SECTION 3: Composition / information on ingredients

### 3.1. Substances

not applicable

### 3.2. Mixtures

This product does not contain any EU-listed substances of very high concern (SVHC) in a concentration of  $\geq 0.1\%$  (Regulation (EC) No 1907/2006 (REACH), Article 59)

(Full text of H- and EUH-statements: see section 16.)

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## SECTION 4: First aid measures

### 4.1. Description of first aid measures

**General information:** First aider: Pay attention to self-protection!  
**In case of inhalation:** Provide fresh air. Seek medical attention if problems persist.  
**Following skin contact:** After contact with skin, wash immediately with plenty of water and soap. In case of skin irritation, consult a physician.  
**After eye contact:** In case of contact with eyes, rinse immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Subsequently consult an ophthalmologist.  
**After ingestion:** Rinse mouth immediately and drink plenty of water. Do NOT induce vomiting. Get medical advice/attention if you feel unwell.

### 4.2. Most important symptoms and effects, both acute and delayed

erythema (redness)

### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

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## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

**Suitable extinguishing media** Co-ordinate fire-fighting measures to the fire surroundings.  
**Unsuitable extinguishing media** Co-ordinate fire-fighting measures to the fire surroundings.

### 5.2. Special hazards arising from the substance or mixture

Not readily flammable

### 5.3. Advice for firefighters

**General information**  
Co-ordinate fire-fighting measures to the fire surroundings.

**Special protective equipment for fire-fighters:**  
In case of fire: Wear self-contained breathing apparatus.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

Remove persons to safety. Remove all sources of ignition. Provide adequate ventilation. Wear personal protection equipment.

### 6.2. Environmental precautions

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

### 6.3. Methods and material for containment and cleaning up

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

### 6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

#### Advices on safe handling

No special measures are necessary.

#### Precautions against fire and explosion:

No special fire protection measures are necessary.

### 7.2. Conditions for safe storage, including any incompatibilities

#### Requirements for storage rooms and vessels

Keep in a cool, well-ventilated place. Do not keep the container sealed.

#### Hints on joint storage

Do not store together with: Acids, alkalines, Powdered metals. Release of: Hydrogen

### 7.3. Specific end use(s)

Observe instructions for use.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### occupational exposure limit value

Substance:	CAS-No.:	Source:	Occupational exposure limit value:[ppm]	Occupational exposure limit value:[mg/m <sup>3</sup> ]	Limitation of exposure peaks:	Remark:

#### Substance with a common (EC) occupational exposure limit value.

Substance:	CAS-No.:	Source:	Occupational exposure limit value:[ppm]	Occupational exposure limit value:[mg/m <sup>3</sup> ]	Limitation of exposure peaks:	Remark:

### DNEL-/PNEC-values

#### DNEL value

Substance:	CAS-No.:	DNEL/DMEL
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#### PNEC Value

Substance:	CAS-No.:	PNEC
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#### Additional information

none

## 8.2. Exposure controls

#### Occupational exposure controls:

Technical measures and the application of suitable work processes have priority over personal protection equipment.

#### General protection and hygiene measures:

When using do not eat, drink, smoke, sniff. Wash hands before breaks and after work. Apply skin care products after work. Wash contaminated clothing prior to re-use.

#### Personal protection equipment

Minimum standard for preventive measures while handling with working materials are specified in the TRGS 500.

#### Respiratory protection

With correct and proper use, and under normal conditions, breathing protection is not required.

#### Hand protection

Tested protective gloves are to be worn: DIN-/EN-Norms: EN ISO 374 Suitable material: Butyl rubber.

#### Eyeface protection

Eye glasses with side protection

#### Body protection:

Wear suitable protective clothing.

#### Environmental exposure controls

refer to chapter 7. No further action is necessary.

#### Consumer exposure controls

refer to chapter 7. No further action is necessary.

#### Exposure Scenario:

Skin contact

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## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

#### Appearance

Physical state:	viscous
Colour:	-
Odour:	odourless
Odour threshold:	No data available

### Safety relevant basis data

	parameter	Value	unit	Remark
Melting point/freezing point:				No data available
Initial boiling point and boiling range:				No data available
Flammability:				No data available
lower flammability or explosive limits:		74	Vol-%	Hydrogen
Upper flammability or explosive limits:		4	Vol-%	Hydrogen
Flash point:	>	150	°C	No data available
Ignition temperature:	>	200	°C	No data available
Decomposition temperature:				No data available
pH:				No data available
Kinematic viscosity:				No data available
Water solubility (g/L):				No data available
Partition coefficient: n-octanol/water:				No data available
Vapour pressure:				No data available
Density:		1,01	g/mL	No data available
Relative density:				No data available
Particle properties:				No data available

## 9.2. Other information

none

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

### 10.2. Chemical stability

With proper storage and handling the product is stable.

### 10.3. Possibility of hazardous reactions

May generate flammable hydrogen gas. Avoid contact with water, alcohols, acidic, basic, or oxidizing materials. Potential for exothermic hazard.

### 10.4. Conditions to avoid

heat. Keep away from sources of ignition - No smoking.

### 10.5. Incompatible materials

Oxidizing agent Acid. Alkalis (alkalis). metal.

### 10.6. Hazardous decomposition products

Hydrogen.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

There are no data available on the preparation/mixture itself.

**M-factor:** - **Acute toxicity (dermal):** -  
**Acute toxicity (oral):** - **Acute toxicity (inhalative):** -

#### Acute toxicity

Substance:	CAS-No.:	Toxicological information
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#### Skin corrosion/irritation:

There are no data available on the preparation/mixture itself.

#### Serious eye damage/irritation:

There are no data available on the preparation/mixture itself.

#### Respiratory or skin sensitisation:

There are no data available on the preparation/mixture itself.

#### CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Carcinogenicity:

No information available.

Germ cell mutagenicity:

No information available.

Reproductive toxicity:

No information available.

#### STOT-single exposure:

No information available.

#### STOT-repeated exposure:

No information available.

#### Aspiration hazard:

There are no data available on the preparation/mixture itself.

## SECTION 12: Ecological information

### 12.1. Toxicity

There are no data available on the preparation/mixture itself.

#### Ecotoxicity

Substance:	CAS-No.:	Ecotoxicity
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### 12.2. Persistence and degradability

There are no data available on the mixture itself.

### 12.3. Bioaccumulative potential

There are no data available on the mixture itself.

### 12.4. Mobility in soil

There are no data available on the mixture itself.

### 12.5. Results of PBT and vPvB assessment

There are no data available on the mixture itself.

### 12.6 Endocrine disruptive effect

There are no data available on the mixture itself.

### 12.7. Other adverse effects

There are no data available on the mixture itself.

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## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

#### Appropriate disposal/Product:

Dispose of waste according to applicable legislation. Waste disposal according to directive 2008/98/EC, covering waste and dangerous waste. Must not be disposed together with household garbage.

#### Appropriate disposal / Package

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

#### List of proposed waste codes / waste designations according to EWC / AVV

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

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## SECTION 14: Transport information

### 14.1. UN number

UN No.: -

### 14.2. UN proper shipping name

Land transport (ADR/RID)

-  
-

Sea transport (IMDG), Air transport (ICAO-TI / IATA-DGR)

-  
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### 14.3. Transport hazard class(es)

Hazard label(s) / Label: - Classification code: / Classification Code: -

### 14.4. Packing group

Packing group/ Packing Group: -

### 14.5. Environmental hazards

ADR/RID / IMDG / ICAO-TI / IATA-DGR:  
Marine pollutant:

Yes

  

No

  

### 14.6. Special precautions for user

Land transport (ADR/RID)

transport category: -

Special provisions: -

tunnel restriction code: -

Limited quantity (LQ): -

**Sea transport (IMDG)**

EmS-No: -

Special provisions: - Limited quantity (LQ): -

**14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Remark -

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**SECTION 15: Regulatory information**

**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

**EU legislation**

**Information on Regulation (EC) No 166/2006 establishing a European Pollutant Release and Transfer Register:**

No information available.

**Regulation (EC) No. 1005/2009 on substances that lead to the depletion of the ozone layer:**

No information available.

**Regulation (EC) No. 648/2004 (Detergents regulation)**

No information available.

**Regulation (EC) No 850/2004 [POP-Regulation]:**

No information available.

**Regulation (EU) No 649/2012 on the export and import of dangerous chemicals:**

No information available.

**Use restriction according to REACH annex XVII, no.::**

No information available.

**National regulations**

Observe in addition any national regulations!

**Restrictions of occupation**

none

**Other regulations, restrictions and prohibition regulations**

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**15.2. Chemical Safety Assessment**

**For this preparation a chemical safety assessment has been carried out.** no

For this substance a chemical safety assessment has not been carried out.

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**SECTION 16: Other information**

**Relevant H- and EUH-phrases (Number and full text):**

**Hazard statements**

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**Training advice**

Observe instructions for use.

**Recommended restrictions of use:**

refer to chapter 1.



#### Further remarks:

The information provided in this safety data sheet is correct to the best of our knowledge at the time of printing. The information is intended to provide guidance on the safe handling of the product specified in this safety data sheet during storage, processing, transport and disposal. The information is not transferable to other products. Insofar as the product is mixed, blended or processed with other materials or undergoes treatment, the information in this safety data sheet cannot be transferred to the new material thus produced, unless expressly stated otherwise.

#### Documentation of changes:

none

#### Key literature references and sources for data

Data arise from reference works and literature.

#### Abbreviations and acronyms

AC: Article Category

ACGIH: American Conference of Government Industrial Hygienists

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road (Accord européen relatif transport des marchandises dangereuses par route)

AOX: Adsorbable Organic halogen compounds

Bw: Body weight

CMR: Carcinogenic, Mutagenic, toxic for Reproduction

CSR: Chemical Safety Report

DIN: Deutsches Institut für Normung (German Institute for Standardization)

DNEL: Derived No Effect Level

DPD: Dangerous Preparations Directive / Directive 1999-45-EC

DSD: Dangerous Substances Directive / Directive 67-548-EC

DU: Downstream User

EC50: Effective Concentration 50%

ECHA: European Chemicals Agency

EN: European Norm

EWC/EWL: European Waste Catalogue

IATA: International Air Transport Association

IBC: Intermediate Bulk Container

ICAO: International Civil Aviation Organization

IMDG Code: International Maritime Dangerous Goods Code

IMO: International Maritime Organization

ISO: International Standards Organisation

LC50: Median Lethal Concentration

LD50: Median Lethal Dose

LEV: Local exhaust ventilation

OEL: Occupational Exposure Limit

PBT: persistent, bioaccumulative, toxic

PNEC: Predicted No Effect Concentration

PPE: Personal Protective Equipment

REACH: Registration, Evaluation and Authorization of Chemicals

RID: Transporting dangerous goods by rail (Règlement International concernant le transport de marchandises dangereuses par chemin de fer)

STEL: Short-term Exposure Limit

SVHC: Substance of Very High Concern

TLV: Threshold Limit Value

VOC: Volatile Organic Compounds

vPvB: very persistent, very bioaccumulative

